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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,916	06/27/2001	Donald R. Ricci	213202.00271	8554

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EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

05

Office Action Summary	Application No.	Applicant(s)	
	09/744,916	RICCI ET AL.	
	Examiner	Art Unit	
	Bruce E Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The final Office action, dated 5/8/03, has been withdrawn; a new rejection follows.

Response to Arguments

Applicant's arguments presented in the Appeal Brief, dated 6/10/04, have been considered but are moot in view of the new ground(s) of rejection.

The rejection in view of Alt et al (5,843,117) has been withdrawn because it was unclear if the teaching that the expanded diameter of 2.5 to about 5.0 mm described a plurality of different diameter stents or just a single stent.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "a porous surface defined by a plurality of interconnecting struts" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32-59 are rejected under 35 U.S.C. 102(b) as clearly anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the Prior Art as defined in applicant's specification including at least page 5, lines 12 et seq.

Applicant's specification teaches: "**[f]or most conventional stents the maximum yield point is reached at a point when the diameter of the expanded stent is about 4 mm to about 5 mm**."

It is the Examiner Examiners position that "about 4 mm" fulfills the claim language of "about 3.5 mm" and even including "about 3.0 mm" as claimed in claim 44.

Regarding any of the specific stent limitations such as "porous surface defined by a plurality of interconnecting struts", coatings, etc., catheters, crimping steps, these limitations are well know in the art and taught in applicant's examples of the prior art, the listing starting on page 2 of the specification.

Regarding applicant claiming, for example claim 33, "*a first unexpanded position," "second pre-expanded position," "third expanded position",* this is merely functional language in which all the prior art stents are fully capable of performing. A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus satisfying the structural limitations of that claimed.

Regarding claim 41, an expanded stent as taught in the prior art inherently is expanded through a pre-expanded position before being expanded to its maximum yield point.

In the alternative, under 35 U.S.C. 103(a) as obvious over the Prior Art

If "about 4 mm" does not fulfill the claim language of "about 3.5 mm" to "about 3.0 mm": It would have been an obvious matter of design choice to have made a smaller diameter stent in the claimed range, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Additionally, it would have been obvious to one having ordinary skill in the art to have made a smaller diameter stent such that it has a maximum diameter correlating to the maximum yield point which is less than or equal to about 3.5 mm such that the stent could be used in smaller patients, children, or simply smaller vessels.

Claims 32-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al (5,843,117).

Alt et al teaches a stent having a distal end and proximal end with a tubular wall disposed there between. Said wall having a plurality of interconnecting struts defining apertures (pores). Alt et al further teaches a fully deployed diameter *"from about 2.5 to about 5.0 mm"*; see column 16, lines 54-65. The fully deployed diameter (5.0 mm of Alt et al) is well known in the art to correspond to approximately the maximum yield point of the stent. (Applicant's specification teaches "*in conventional stents.. it is generally desirable to deploy the stent to a diameter which is as close as possible to, but does not exceed, the maximum yield point.*" See applicant's specification page 4, lines 25 et seq.)

It would have been an obvious matter of design choice to have made a smaller diameter stent in the claimed range, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Additionally, it would have been obvious to one having ordinary skill in the art to have made a smaller diameter stent such that it has a maximum diameter correlating to

the maximum yield point which is less than or equal to about 3.5 mm such that the stent could be used in smaller patients, children, or simply smaller vessels.

Regarding applicant claiming, for example claim 33, "*a first unexpanded position,*" "*second pre-expanded position,*" "*third expanded position*", this is merely functional language in which the stent of Alt et al is fully capable of performing. A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus satisfying the structural limitations of that claimed. The device disclosed by Alt et al fulfills the metes and bounds of the claim specified by the applicant and is fully capable of the performing the intended function. Additionally, Alt et al teaches a "pre-expanded position" (termed partial expansion or pre-opening); see column 8, lines 17 et seq. and column 15, lines 39 et seq.

Regarding claim 34, Alt et al teaches 2.0 to 2.3 mm. See column 15, line 58.

Regarding the first unexpanded position having a diameter of less than or equal to about 1.1 mm, Alt et al teaches about 1.6 mm **as an example**. It is the Examiner position that "about 1.6 mm" meets the claim limitation of "about 1.0 mm". Further, 1.6 mm diameter is only an example is believed to correspond to the a fully expanded diameter of 5-6 mm. Inherently, a stent having a fully expanded diameter of about 2.5 mm would have a first unexpanded diameter of about 0.5 to 1.0 mm.

Regarding claim 41, "A partially expanded stent," the device of Alt et al inherently can be "partially expanded stent" and does have a pre-expanded position as described above.

Regarding claims 45-55, see column 4, lines 17-30; column 4, lines 52-67; column 16, lines 54 et seq. Regarding claims 49-53 claiming a "mandrel" or "die"; Alt et al teaches a "needle" interpreted as the same device.

Claims 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al (5,843,117).

Alt et al teaches the stent as described above, however, is unclear as having a medicinal coating on the wall. Medicinal coatings on stents are well known in the art and would have been obvious to one having ordinary skill to have used any know coatings on the stent of Alt et al for improved acceptance by the body, etc.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

bes
November 9, 2004

BRUCE SNOW
PRIMARY EXAMINER